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Comparison of glistenings formation and their effect on forward light scatter between the Acrysof SN60WF and Eternity Natural Uni NW-60 intraocular lenses

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ABSTRACT

Aims To compare the characteristics of glistenings and forward light scatter between the Alcon Acrysof SN60WF and Santen Eternity Natural Uni NW-60 intraocular lenses (IOLs).

Methods Five Acrysof SN60WF and five Eternity Natural Uni NW-60 IOLs were studied. All IOLs were single piece blue blockers with the same dioptric power (20D) and optic diameter (6.0 mm). Glistenings were induced by a thermal accelerated ageing process. Glistenings were objectively quantified using bespoke image processing software. The angular distribution of forward light scatter was measured using an optical bench system and the straylight parameter calculated from the light scatter function.

Results The median increase in the number of glistenings was 15 and 525 for the Eternity and Acrysof IOLs, respectively, which was statistically significantly different ($p=0.012$). Median glistenings diameter was 23.8 µm (Acrysof) and 32.8 µm (Eternity). Four (80%) of the Acrysof lenses had straylight values higher than a 20-year-old CIE standard glare observer and in two cases the straylight exceeded that of the 70-year-old CIE standard glare observer. None of the Eternity lenses had straylight values that exceeded the value for the 20-year-old CIE standard glare observer.

Conclusions The Eternity Natural Uni NW-60 IOLs resisted the induction of glistenings more than the Acrysof SN60WF IOLs. Although the Acrysof IOLs developed smaller glistenings than the Eternity IOLs, there were sufficient numbers to produce a higher straylight parameter.

INTRODUCTION

Glistenings have been observed in all types of intraocular lens (IOL) materials,¹ although hydrophobic acrylic polymers, the most commonly used IOL material,² appear to be more susceptible to their formation.³ Factors affecting glistenings formation are not completely understood but manufacturing methods^{1–5} and packaging^{6–9} might influence their development in addition to the material itself.

Key messages

What is already known about this subject?

- ▶ Manufacturers have improved materials and the manufacturing process with the aim of producing 'glistenings-free' intraocular lenses (IOLs).
- ▶ There is a lack of independent, comparative data that evaluates and characterises the occurrence and size of glistenings in new IOL materials.

What are the new findings?

- ▶ In laboratory tests, Eternity Natural Uni NW-60 IOLs produced significantly fewer glistenings but of larger size compared with Acrysof SN60WF.

How might these results change the focus of research or clinical practice?

- ▶ Different materials produce glistenings of different size and density.
- ▶ Size and density of glistenings interact to affect the optical and therefore potential visual consequences of glistenings.

Acrysof was the first commercially available hydrophobic acrylic IOL. Since its introduction clinically in 1995, over 40 million such IOLs have been implanted globally.^{1 7 8 10–17} These lenses have been shown to be associated with significant glistenings formation following implantation. Indeed, Colin *et al*,¹⁸ reported that out of 111 eyes implanted with the Acrysof SN60WF IOL, 96 (86.5%) of them developed glistenings despite following manufacturing changes, reduction although not complete elimination of glistenings has been reported.¹⁹

Over recent years manufacturers have endeavoured not only to reduce glistenings density but to try to eliminate them completely. A recent in vivo comparison between two, single piece hydrophobic acrylic IOLs, the Acrysof SN60WF and iMics1 NY-60, found no glistenings in the iMics1 NY-60 IOLs

compared with the Acrysof SN60WF.²⁰ No comparative studies on the development of glistenings in the Eternity Natural Uni NW-60 IOL have been published to date. The enVista IOL, manufactured by Bausch and Lomb using the same material as the Eternity Natural Uni, has been clinically reported as a glistening-free hydrophobic acrylic material,²¹ which suggests that the Eternity Natural Uni NW-60 IOL could also be glistening free or develop significantly fewer glistenings.

In contrast to the occurrence of glistenings, there are few reports characterising their diameter. Glistenings have been reported up to a diameter of 20 µm in Acrysof IOLs.^{13–22} A comparison study between Acrysof (Alcon) and Sensar (Allergan Medical Optics) showed the diameter of glistenings varied between the two materials, with the latter developing glistenings up to 21.7 µm.²³ An in vitro study by van der Mooren *et al* found that glistenings in the enVista (Bausch and Lomb) IOL had a diameter of approximately 33 µm and the Tecnis (Abbott) IOL 25 µm, while the diameters of glistenings induced in the iSymm (Hoya) and Acrysof (Alcon) IOLs were significantly smaller at 5.2 µm and 6.2 µm, respectively.²⁴ The Santen Eternity Natural Uni NW-60 IOL has not been evaluated for diameter of glistenings to our best knowledge and the only comparison study found evaluated the uveal and capsular biocompatibility of the Eternity Natural Uni NW-60 as a new hydrophobic acrylic material.²⁵ Glistenings number and size both affect straylight and are therefore important in evaluating IOL performance.

The primary aim of our study was to carry out the first independent evaluation of glistenings' formation and their effect on straylight between the Alcon Acrysof SN60WF and Santen Eternity Natural Uni NW-60 IOLs, both current, commercially available IOLs. A secondary aim was to evaluate the diameters of glistenings in these two materials.

MATERIALS AND METHODS

Intraocular lenses

Five Alcon Acrysof SN60WF (hereinafter referred to as Acrysof) and five Santen Eternity Natural Uni NW-60 (hereinafter referred to as Eternity) IOLs were studied. The IOLs were delivered in October 2013, in sealed packages as provided by the manufacturer. The Eternity Natural Uni NW-60 lenses were all manufactured in 2013 following their release and the Alcon Acrysof SN60WF IOLs between February and September 2011. Once the IOLs were removed from their packaging they were kept immersed in saline solution at a constant temperature of 35°C to ensure that all lenses were fully hydrated prior to glistenings induction and light scatter measurements.

Light scatter measurements

The laboratory set-up for measuring the forward light scatter of IOLs is shown in figure 1. In brief, the IOL was mounted within a cuvette (fluorimeter cell; Starna Scientific, Hainault, UK) containing saline at the centre

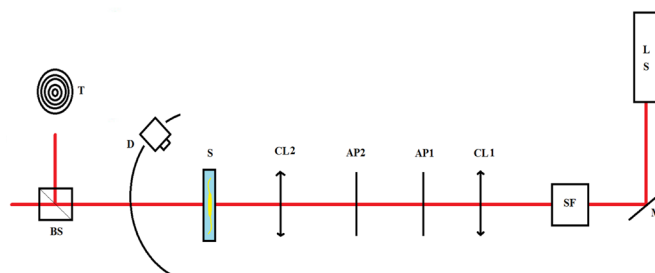


Figure 1 Experimental setup. AP (1 and 2), apertures; BS, cube beam splitter; CL1, achromatic collimating lens; CL2, achromatic lens; D, detector; LS, monochromatic light source; M, mirror; S, intraocular lens sample stage; SF, spatial filter; T, target.

of rotation of a detector. The cuvette had optical quality walls to minimise its contribution to forward light scatter. A He-Ne laser (wavelength 543 nm, 0.634 mW; Spindler and Hoyer, Göttingen, Germany) was expanded by the spatial filter and collimated by an aberration-corrected doublet (CL1) before the beam was 'top-hatted' by aperture AP1 to produce a uniform beam. The beam passes through a second aperture, AP2, that controls the diameter of the illuminated area of the IOL before being focused by a second aberration-corrected doublet (CL2) at the front focal point of the IOL to compensate for its power. The beam diameter at the IOL could be adjusted using aperture AP2 between 3 and 5 mm representing a mid-range of physiological pupil sizes. The detector, comprising a microscope objective, pinhole and photodiode to provide strong angular dependence, was rotated to measure the scattered light over an angle of $\pm 18^\circ$ using 37 steps with more readings taken near the peak where the scatter function changes rapidly. IOLs were measured after the induction of glistenings. The volume under the measured scatter function was normalised so that it represented the CIE point spread function, $PSF(\theta)$.²⁶ The straylight parameter, $s(\theta)$, was then calculated from

$$s(\theta) = \theta^2 \times PSF(\theta) \quad (1)$$

where θ is the scattering angle. A value of 10° was chosen for θ since it approximates the eccentricity of the glare source in the C-Quant straylight metre.^{27–29} For comparison, the straylight parameter was calculated for a 20-year-old and 70-year-old CIE Standard Glare Observer with pigmentation factor, $p=1$ for blue-green Caucasian irides.

Objective assessment of glistenings

IOL images were obtained using the biomicroscope on a Nikon FS-2 photo slit-lamp and Nikon D90 digital camera. The biomicroscope was adjusted to focus the edge of the IOL with the IOL centred in the field of view. Magnification was set to 30× to ensure that the tested IOL covered as much of the image as possible. The image sizes were 8.8×5.9 mm in object space with a resolution of 365 pixels/mm. Glistenings exist within the volume of the IOL where the axial thickness varies but is of the order of 0.6 mm. Calculations based on biomicroscope

parameters, indicate a 0.4 mm depth of focus. This is the range of depth over which glistenings appear equally sharp. Outside this range there is a gradual decrease in sharpness. The lens was illuminated with a custom-made light-emitting diode source from below at an angle of 30° to the optical axis of the IOL. Eight to ten images were captured for each of the tested IOLs pre-treatment and post-treatment. The images were subjectively assessed for uniformity and focus and the best selected for objective quantification of glistenings using bespoke image processing software developed for this work.³⁰ The software semiautomatically scanned the images and detected glistenings before and after treatment.

Induction of lens glistenings

To induce lens glistenings, all IOLs were immersed in 0.9% saline and maintained at 50°C for 5 days. Thereafter the IOLs were kept at a constant temperature of 35°C.

Statistical analysis

Due to the small sample sizes, non-parametric statistics were used. All analyses were carried out using Minitab Release V.14.2 (State College, Pennsylvania, USA). The level of statistical significance was set at 5%.

Patient and public partnership

No patients or members of the public were involved in this study.

RESULTS

The total number of glistenings developed by each IOL group following thermal induction is shown in figure 2. The median increase in the number of glistenings for the Eternity IOLs was 15 (range 4–65) compared with

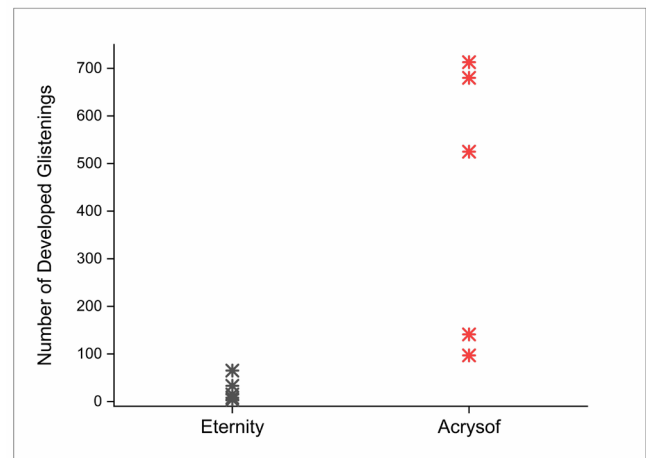


Figure 2 Number of developed glistenings, post-treatment, for each intraocular lens material.

525 (range 97–713) for the Acrysof group. This difference was statistically significant ($p=0.012$; Mann-Whitney test). The large spread of values in the Acrysof lenses post-treatment indicates that not all lenses developed glistenings to the same extent (figure 2).

Distribution of the diameters of all glistenings present in all five lenses for the two different IOL materials post-treatment is shown in figure 3. The Eternity IOLs developed a larger proportion of 20–40 μm diameter glistenings, with a median of 32.8 μm compared with the Acrysof lenses, which developed a higher proportion of 1–20 μm size glistenings (median diameter of 23.8 μm). Figures 2 and 3 demonstrate that number and diameters of glistenings vary.

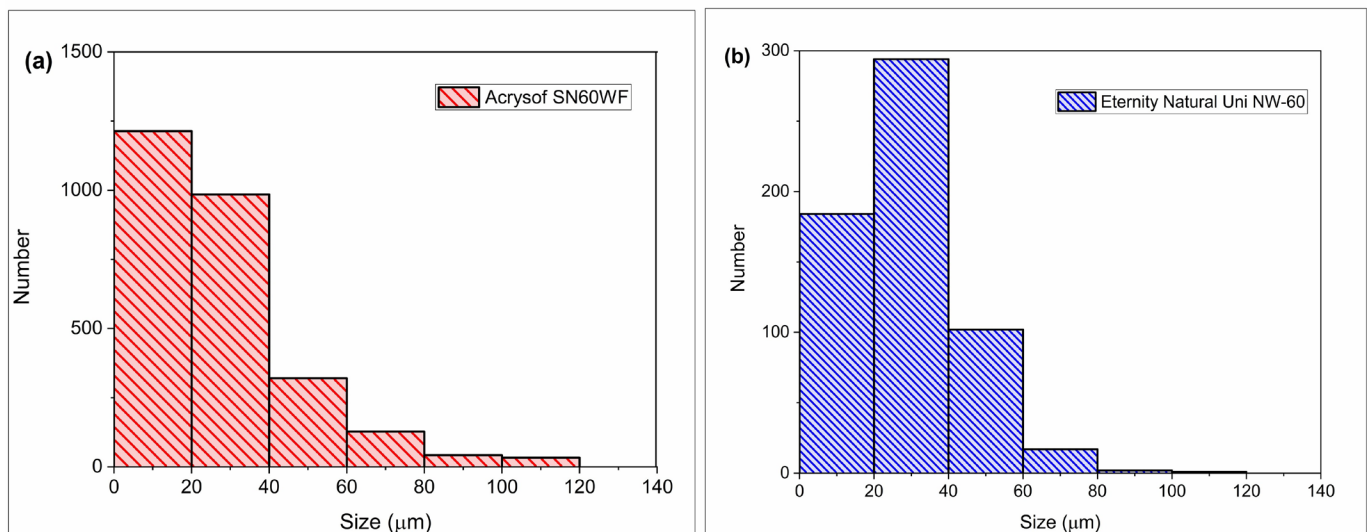


Figure 3 Distribution of the diameters of all detected glistenings for the two different materials (data pooled from all lenses within each intraocular lens group); (a) Acrysof and (b) Eternity Natural Uni.

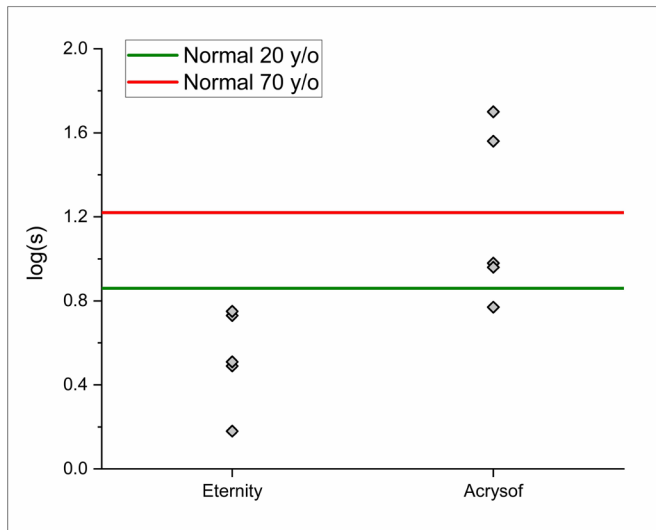


Figure 4 Log straylight parameter values at 10° eccentricity for each tested intraocular lens post-treatment. The log(s) values for the CIE young and old observer are 0.86 (green) and 1.22 (red), respectively.²⁶

Log straylight values for 10° eccentricity were found to be less than the 20-year-old CIE standard glare observer in all cases for the Eternity Natural Uni lenses (figure 4). In comparison, log straylight values for the Acrysof lenses were higher than for the Eternity IOLs although there was significant variation with two out of five cases being greater than the 70-year-old CIE standard glare observer. Angular distribution of forward light scatter and its comparison with the 20-year-old and 70-year-old CIE standard glare observers is shown in figure 5.

DISCUSSION

Results from our study demonstrate a significant difference in the development of glistenings between the

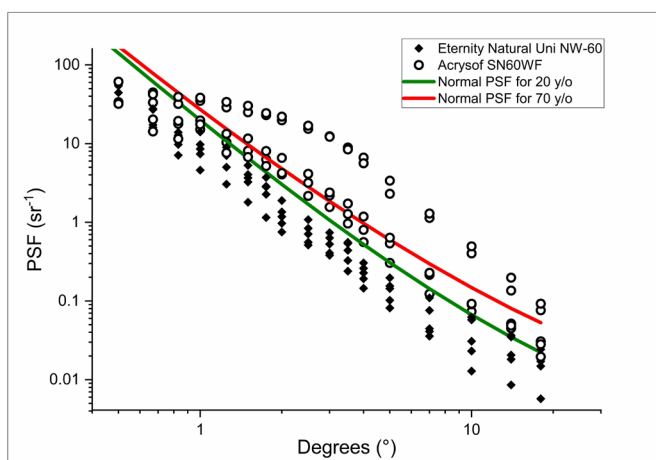


Figure 5 Angular distribution of forward light scatter. The green line represents the straylight for a young 20-year-old subject while the red line that of a 70-year-old according to the CIE standard glare observer. Open circles represent data for the five Acrysof intraocular lenses (IOLs) whereas the solid diamonds represent data for the five Eternity Natural Uni IOLs.

Acrysof SN60WF and Eternity Natural Uni NW-60 IOLs. The results support the hypothesis that differences in the material properties are likely to play a role in glistenings formation.

Forward light scatter for the Acrysof lenses was higher than for the Eternity Natural Uni lenses indicating an association between forward light scatter and increased number of glistenings in agreement with theoretical models.³¹ However, the question of whether the impact on vision is clinically significant remains unclear. Comparison with values derived from the CIE standard glare observer, indicate that for two studied Acrysof IOLs the straylight parameter exceeds that of a 70 years old glare observer. The measured log straylight values for these same two IOLs also exceeded the straylight parameter for a subject with cortical cataract.³² This result is surprising and needs careful evaluation. Scattering theory tells us that although smaller particles generate a more uniform angular distribution of scattered light, they also produce a lower straylight parameter for equivalent density values compared with larger particles. The results and model of Łabuz *et al*³¹ indicate that to achieve a straylight value of 1.5 would require 7000 glistenings/mm² if the average glistenings' diameter was 5 µm. However, if the average glistenings size increases to 15 µm, a straylight parameter closer to the results we report is produced by just under 1000 glistenings/mm². Indeed, our measured median glistenings diameters were larger at 23.8 µm (Acrysof) and 32.8 µm (Eternity) implying that similar levels of straylight to those measured could be produced by glistenings density values in the hundred per mm². This, however, is only a partial explanation because our detected glistenings density values were on average 10 and 71 glistenings/mm² for the Eternity and Acrysof lenses, respectively. Careful re-examination of the two Acrysof lenses with higher straylight values indicated the presence of small, out of focus irregularities that were not detected by our glistenings detection software, which could be subsurface nano-glistenings. It is possible that these degradations could increase the level of straylight. It also remains possible that system scatter could increase measured straylight values and so log straylight parameter values were calculated for clear IOLs and found to be 0.51±0.14. However, this level of straylight has minimal effect on the log(s) values for the IOLs measured in our study. It also indicates that the Eternity lenses produced negligible levels of straylight after induction of glistenings in line with expectations if there are, on average, only 10 glistenings/mm². In conclusion, we believe our results are valid and explained by the effect of glistenings diameter as well as number and possibly the presence of subsurface nano-glistenings that are not quantified by the glistenings detection programme.

The highest frequency of the glistenings that developed in the Acrysof material were less than 20 µm (figure 3), in agreement with previous studies.^{13 19 22 23} The presence of larger diameter glistenings may be linked to the thermal induction process.^{22 33} The Eternity Natural Uni

IOL material, although less susceptible to developing glistenings, was more likely to develop larger glistenings (greater than 20 μm). This result indicates that not only the number but the size of glistenings differs among materials (figures 2 and 3), as has also been noted by other authors.²⁴ Glistenings density values reported here have been compared with clinical studies and found to be in broad agreement based on the range found in subjective grading scales^{23 34} as well as other clinical studies that have directly reported glistenings density values.^{19 22 29} Reports of glistenings' diameter from clinical studies are limited and to our best knowledge only Henriksen *et al* have reported values with a range from 6 to 35.7 μm .³⁵ The glistenings diameters reported in our study are higher but it would be difficult to draw strong conclusions due to the lack of comparative evidence.

The wide variation in the number of developed glistenings among Acrysof IOLs may indicate changes in the manufacturing process. In 2012, Alcon reported a continuous improvement of its manufacturing process, including environmental controls, cast moulding and curing operations.¹⁹ The exact details of these improvements remain undisclosed for commercial reasons. As reported in our methodology, the Acrysof lenses used in this current study were manufactured between February and September 2011. However, it is not clear whether the IOLs were manufactured before, during or after the reported manufacturing improvements. Consequently, our results on the Acrysof IOLs should be interpreted cautiously.

The results from this study hint at the role material properties play in the development of glistenings. However, we do not infer a causal relationship because of other potential explanatory variables: the two IOLs evaluated are supplied in different packaging, one dry (Acrysof) and the other hydrated (Eternity). Dry packaging has been associated with glistenings formation⁷⁻⁹ although there is no association when the IOL is hydrated.⁶ Our results also clearly demonstrate how diameter and number of glistenings affect forward light scatter; in this case the larger number of smaller glistenings in the Acrysof material produced more straylight than the small number of larger glistenings in the Eternity IOLs even though larger glistenings in general cause more straylight. This is because the scatter is more directional so more light is scattered towards the retina. The results are most useful for informing materials development and generating further hypotheses for clinical studies that should lead to an evidence-base for clinical advice and management.

The experimental design of our study had several strengths. These include the objective quantification of glistenings parameters, the before and after design so that differences can be analysed and the systematic way in which all samples were handled reducing variability. However, there are some limitations to our study the most significant of which was the small number of lenses analysed. This was compensated partially by the before and after design allowing the analysis of differences.

More importantly the measured difference between the two materials was large enough even at the sample size used to reach significance. Increasing the sample size would therefore be unlikely to change the main results and conclusions. A further limitation we noted was that the glistenings detection software reported optical artefacts as glistenings prior to thermal induction. From analysis of the images, we suspect these are most likely false glistenings, appearing at the edges of the IOL optic although we cannot rule out the possibility that some glistenings may develop in the lens materials during the manufacturing process and while in packaging and storage. Again, analysing the differences from baseline helps to compensate for any artefacts if they are detected as glistenings by the software.

In vitro studies are open to the criticism that their results may not extend to the clinical domain thereby lacking relevance to clinical decision making and management. It is not known for certain if accelerated thermal ageing, widely used in in vitro studies, produces clinically relevant results. Reported temperatures for accelerated ageing vary from 23°C to 70°C with the protocol for time spent at different temperatures also varying widely. We do not therefore infer a clear clinical meaning to our results and further clinical studies should be carried out to support our conclusions.

The findings from this study suggest avenues for future research. Previous studies have demonstrated an increase in light scatter with increased numbers of glistenings. However, the interaction with glistenings size is more complex with larger glistenings producing greater levels of straylight.³¹ The threshold in terms of size and density of glistenings at which there is a measurable effect on visual performance remains unclear. The possibility of objectively quantifying glistenings in in vivo images coupled with sensitive tests of vision that move away from high contrast acuity in a clinical trial would be advantageous and is currently being pursued by the authors. Further data on the association of glistenings parameters with visual performance could better inform clinical advice and management in symptomatic cases.

In conclusion, this laboratory study has demonstrated that different IOL materials produce varying density and size of glistenings, which both influence straylight. Our results imply that the threshold at which visual performance is affected could vary. Choice of IOL material should consider the development of glistenings alongside other material properties such as biocompatibility.

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Contributors EP: laboratory work, data analysis, manuscript preparation. CH: PI, manuscript preparation. DPO'B: manuscript preparation.

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